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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,779	09/23/2004	Yoshihiko Masaki	40072-0011	8473

26633 7590 08/30/2006

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EXAMINER	
STITZEL, DAVID PAUL	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/508,779	MASAKI ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

OFFICIAL ACTION

Acknowledgment of Receipt

Receipt of the Applicants' Response, which was filed on May 25, 2006, in response to the Official Action dated January 25, 2006, is acknowledged.

Status of Claims

Claim 5 was canceled, and claims 1, 6, 7, 10 and 12-17 were amended by an amendment that accompanied the aforementioned Response. As a result, claims 1-4 and 6-17 are currently pending and therefore examined herein on the merits for patentability.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejections as set forth under this particular section of the Official Action:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. The rejection of claims 12-17 under 35 U.S.C. § 101 is hereby withdrawn in light of Applicants' claim amendments reciting statutorily proper process claims.

2. Claims 12-17 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, because a claim is rendered indefinite when said claim merely recites a use without any active, positive steps delimiting how this use is actually practiced. See MPEP 2175.03(q). More specifically, claims 12-17 provide for a method of making a composition comprising an inulin type fructan, but because said claims do not set forth any steps involved in the method or process, it is unclear what method or process Applicants are intending to encompass. As a result, the Applicants are

required to either cancel or redraft the aforementioned use claims as statutory process claims that delimit active, positive steps (i.e., preparing, dissolving, adding) on how to make a composition according to the invention as originally filed.

3. Claim 10 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. With respect to claim 10, confusion exists as to whether Applicant is claiming a method for improving damage to an organ during an organ transplantation process, as said claim recites "***A method for*** suppressing or ***improving*** hypofunction of and ***damage to an organ*** during an organ transplantation process." Emphasis added. As a result, claim 10 is rendered indefinite because the meets and bounds of said claim is unclear, as confusion exists with respect to the intended scope of said claim. See MPEP § 2173. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 102

1. The rejection of claims 1-4, 7 and 12-17 under 35 U.S.C. § 102(b) as being anticipated by Japanese Patent Application Publication 07-099965 (hereinafter the Matsumoto '965 publication) is hereby withdrawn in light of Applicants' claim amendments incorporating the claim limitations of dependent claim 5 into independent claim 1.

2. The rejection of claims 1, 7-11, 12, 16 and 17 under 35 U.S.C. § 102(b) as being anticipated by Japanese Patent Application Publication 08-034701 (hereinafter the Shigematsu '701 publication) is hereby withdrawn in light of Applicants' claim amendments incorporating the claim limitations of dependent claim 5 into independent claim 1.

Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. The rejection of claims 1, 5 and 6 under 35 U.S.C. § 103(a) as being unpatentable over Japanese Patent Application Publication 06-040801 (hereinafter the Wada '801 publication) in view of Japanese Patent Application Publication 05-038284 (hereinafter the Takama '284 publication) is hereby withdrawn in light of Applicants' claim amendments incorporating the claim limitations of dependent claim 5 into independent claim 1 and the new grounds of rejection as set forth hereinbelow.

2. Claims 1, 3, 4, 6-12 and 14-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Japanese Patent Application Publication 06-040801 (hereinafter the Wada '801 publication) in view of Japanese Patent Application Publication 05-038284 (hereinafter the Takama '284 publication).

With respect to claims 1, 3, 6-12 and 14-17 of the instant application, the Wada '801 publication teaches an organ transplant preservation perfusion solution for preserving organ function, a method of using said organ transplant preservation perfusion solution to preserve organs, and a method of making said organ transplant preservation perfusion solution, wherein said organ transplant preservation perfusion solution comprises: starch present at a concentration from 0 g/L to 80 g/L; sodium cation present at a concentration from 10 mM to 140 mM; potassium cation present at a concentration from 4 mM to 140 mM; magnesium cation present at a concentration from 0 mM to 4

mM; calcium cation present at a concentration from 0 mM to 2 mM; dihydrogen phosphate anion or hydrogen phosphate anion present at a concentration from 12 mM to 65 mM; and at least one component present at a concentration from 15 mM to 150 mM and selected from the group consisting of: chloride anion; hydrogen carbonate anion; carbonate anion; organic acids; and organic anions; wherein said organ may include a lung (page 5, [0001] and [0003]; page 6, [0005]; page 7, [0006]-[0008]; page 9, [0016]; claim 1).

Although the Wada '801 publication teaches utilizing starch present at a concentration from 0 g/L to 80 g/L within said organ transplant preservation perfusion solution, the Wada '801 publication does not explicitly teach utilizing an inulin fructan oligosaccharide within said organ transplant preservation perfusion solution, as instantly claimed.

However, the Takama '284 publication teaches a preservation solution for preserving live cells (page 5, [constitution]; claims 1 and 2), a method of using said preservation solution to preserve live cells (claim 1), and a method of making said preservation solution (page 7, [0007]; page 10, [0011]), wherein said preservation solution for preserving live cells comprises: (1) a 1-ketose inulin fructan oligosaccharide (page 8, [0010]; page 9, [0010]; claims 1 and 2) and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides (page 10, [0011]); and (2) an optional additional preservation solution (page 5, [constitution]; page 10, [0012]; page 19, [0030]).

Although the Takama '284 publication teaches a preservation solution for preserving live cells comprising: (1) a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides; and (2) an optional additional preservation solution, the Takama '284 publication does not explicitly teach specific ingredients comprising said optional additional preservation solution and that said preservation solution is useful for preserving not only live cells, but also organs, as instantly claimed.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute for the starch ingredient present within the organ transplant preservation perfusion solution of the Wada '801 publication, a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides, since not only is starch a polymer of glucose sugars, but also 1-ketose and nystose inulin fructan oligosaccharides are likewise polymers of glucose sugars, as well as fructose sugars, as reasonably suggested by the Takama '284 publication. One of ordinary skill in the art at the time the instant application was filed would have been motivated to substitute a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides within the preservation solution of the Takama '284 publication, for the starch ingredient within the organ transplant preservation perfusion solution of the Wada '801 publication, since a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides are also useful for preserving live cells, as reasonably suggested by the Takama '284 publication. One of ordinary skill in the art at the time the instant application was filed would have had a reasonable expectation of success in doing so since organs are simply an aggregation of a plurality of live cells having a specialized function.

3. Claims 2 and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Japanese Patent Application Publication 06-040801 (hereinafter the Wada '801 publication) in view of Japanese Patent Application Publication 05-038284 (hereinafter the Takama '284 publication) and in further view of Japanese Patent Application Publication 07-099965 (hereinafter the Matsumoto '965 publication).

The teachings of the Wada '801 publication and the Takama '284 publication are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 2 and 13 of the instant application, neither the Wada '801 publication, nor the Takama '284 publication explicitly teach a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides having a specific degree of polymerization from 3 to 6, as instantly claimed.

However, the Matsumoto '965 publication teaches a composition for protecting live cells from frost damage comprising: (1) an inulin fructan oligosaccharide and/or a mixture of two or more inulin fructan oligosaccharides having a degree of polymerization of from 3 to 6 (page 10, [0011]; page 14, [0019]; page 15, [0021]; claims 2, 3, 6 and 7); and (2) an optional additional preservation composition (page 9, [0008], [0010], [0011]); wherein said inulin fructan oligosaccharide and/or mixture of two or more inulin fructan oligosaccharides is selected from the group consisting of: a 1-kestose inulin fructan oligosaccharide having a degree of polymerization of 3; and a nystose inulin fructan oligosaccharide having a degree of polymerization of 4 (page 6, [0001]; page 7, [0003]; page 8, [0005]-[0006]; page 9, [0008], [0010], [0011]; page 10, [0011]-[0012]; page 11, [0013]; page 14, [0019]; page 15, [0021]; page 19, [0028]; Claims: 1-7).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to incorporate for the 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides present within the organ transplant preservation perfusion solution of the Wada '801 publication, an inulin fructan oligosaccharide and/or a mixture of two or more inulin fructan oligosaccharides having a degree of polymerization of from 3 to 6; wherein said inulin fructan oligosaccharide and/or mixture of two or more inulin fructan oligosaccharides is selected from the group consisting of: a 1-kestose inulin fructan oligosaccharide having a degree of polymerization of 3; and a nystose inulin fructan oligosaccharide having a degree of polymerization of

4, which is/are present within said composition for protecting live cells from frost damage, as reasonably suggested by the Matsumoto '965 publication.

One of ordinary skill in the art at the time the instant application was filed would have been motivated to substitute an inulin fructan oligosaccharide and/or a mixture of two or more inulin fructan oligosaccharides having a degree of polymerization of from 3 to 6; wherein said inulin fructan oligosaccharide and/or mixture of two or more inulin fructan oligosaccharides is selected from the group consisting of: a 1-kestose inulin fructan oligosaccharide having a degree of polymerization of 3; and a nystose inulin fructan oligosaccharide having a degree of polymerization of 4, which is/are present within said composition for protecting live cells from frost damage, as reasonably suggested by the Matsumoto '965 publication, for the 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides present within the organ transplant preservation perfusion solution of the Wada '801 publication, since the Matsumoto '965 publication reasonably suggests that said composition is particularly useful for protecting live cells from frost damage, wherein said composition comprises: an inulin fructan oligosaccharide and/or a mixture of two or more inulin fructan oligosaccharides having a degree of polymerization of from 3 to 6; wherein said inulin fructan oligosaccharide and/or mixture of two or more inulin fructan oligosaccharides is selected from the group consisting of: a 1-kestose inulin fructan oligosaccharide having a degree of polymerization of 3; and a nystose inulin fructan oligosaccharide having a degree of polymerization of 4. One of ordinary skill in the art at the time the instant application was filed would have had a reasonable expectation of success in doing so since organs are simply an aggregation of a plurality of live cells having a specialized function.

Examiner's Response to Applicant's Remarks

Although Applicants' arguments as set forth in the aforementioned Response have been fully considered in light of the claims as currently amended, they are not persuasive. Applicant's claim amendments necessitated the new grounds of rejection as set forth hereinabove.

1. 35 U.S.C. § 103(a) rejection based on Japanese Application Publication 06-040801 (hereinafter the Wada '801 publication) in view of Japanese Application Publication 05-038284 (hereinafter the Takama '284 publication).

Applicant argues on pages 7-8 of the aforementioned Response, that the Wada '801 publication teaches an organ transplant preservation perfusion solution for preserving organ function comprising trehalose. Applicant also argues on pages 8-9 of the aforementioned Response, that the Takama '284 publication teaches a preservation solution for preserving live cells, not organs, and as such is non-analogous art.

In response to Applicants' argument, in addition to containing trehalose, the Wada '801 publication also teaches an organ transplant preservation perfusion solution for preserving organ function further comprising starch, which is present at a concentration from 0 g/L to 80 g/L.

Although the Wada '801 publication teaches utilizing starch present at a concentration from 0 g/L to 80 g/L within said organ transplant preservation perfusion solution, the Wada '801 publication does not explicitly teach utilizing an inulin fructan oligosaccharide within said organ transplant preservation perfusion solution, as instantly claimed.

However, the Takama '284 publication teaches a preservation solution for preserving live cells (page 5, [constitution]; claims 1 and 2), a method of using said preservation solution to preserve live cells (claim 1), and a method of making said preservation solution (page 7, [0007]; page 10, [0011]),

wherein said preservation solution for preserving live cells comprises: (1) a 1-ketose inulin fructan oligosaccharide (page 8, [0010]; page 9, [0010]; claims 1 and 2) and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides (page 10, [0011]); and (2) an optional additional preservation solution (page 5, [constitution]; page 10, [0012]; page 19, [0030]).

Although the Takama '284 publication teaches a preservation solution for preserving live cells comprising: (1) a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides; and (2) an optional additional preservation solution, the Takama '284 publication does not explicitly teach specific ingredients comprising said optional additional preservation solution and that said preservation solution is useful for preserving not only live cells, but also organs, as instantly claimed.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute for the starch ingredient present within the organ transplant preservation perfusion solution of the Wada '801 publication, a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides, since not only is starch a polymer of glucose sugars, but also 1-ketose and nystose inulin fructan oligosaccharides are likewise polymers of glucose sugars, as well as fructose sugars, as reasonably suggested by the Takama '284 publication. One of ordinary skill in the art at the time the instant application was filed would have been motivated to substitute a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides within the preservation solution of the Takama '284 publication, for the starch ingredient within the organ transplant preservation perfusion solution of the Wada '801 publication, since a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides are also useful for preserving live cells, as reasonably suggested by the Takama '284 publication. One of ordinary skill in the art at the time the instant

application was filed would have had a reasonable expectation of success in doing so since organs are simply an aggregation of a plurality of live cells having a specialized function.

Applicants' argument that a prior art reference that teaches an organ transplant preservation perfusion solution for preserving organ function in non-analogous art in relation to a prior art reference that teaches a preservation solution for preserving live cells is unpersuasive. Organs are simply an aggregation of a plurality of live cells having a specialized function. Therefore, the Wada '801 publication, which teaches an organ transplant preservation perfusion solution for preserving organ function on a cellular level, is in fact analogous art in relation to the Takama '284 publication, which teaches that a preservation solution for preserving live cells.

As a result, Claims 1-4 and 6-17 stand rejected because the claimed invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made since each and every element of the claimed invention, as a whole, would have been reasonably suggested by the teachings of the cited prior art references.

Remarks

The following is a list of foreign prior art patent application publications made of record and considered pertinent to the Applicant's disclosure, but are not however currently relied upon in construing the claim rejections as set forth herein:

- Japanese Patent Application Publication 09-255501 (hereinafter the Yoshimizu '501 publication); and

- Japanese Application Publication 08-034701 (the Shigematsu '701 publication teaches a preservation perfusate composition comprising an inulin, and ***a method for preserving a live cell and organ*** by ***maintaining the property and function of said live cell and organ on a cellular level***, wherein said method comprises perfusing said cell and/or said organ with said preservation perfusate composition comprising an inulin; ***wherein said live cell includes, sperm and microorganisms; wherein said organ includes, but is not limited to, a mammalian liver, kidney, spleen and brain*** (Detailed Description: [0003], [0004], [0009], [0019]; Industrial Application; Effect of the Invention; Means for Solving the Problem: [0019]; Claims: 1 and 3).

Conclusion

Applicant's claim amendments necessitated the new grounds of rejection presented in this Official Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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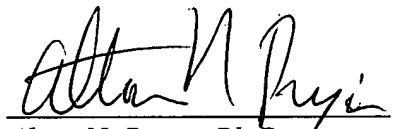

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